NYSTATIN- nystatin ointment
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

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NYSTATIN OINTMENT USP
Rx only

DESCRIPTION
Nystatin Ointment USP, for topical use only, contains 100,000 USP Nystatin Units per gram, in a polyethylene and mineral oil base. The structural formula is as follows:

![Structural formula of Nystatin](image)

Molecular Weight 926.13
Molecular Formula C_{47}H_{75}NO_{17}

CLINICAL PHARMACOLOGY
Nystatin is an antifungal antibiotic which is both fungistatic and fungicidal in vitro against a wide variety of yeasts and yeast-like fungi. It probably acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin is a polyene antibiotic that is obtained from *Streptomyces noursei*, and is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous, oral and intestinal infections caused by *Candida* [Monilia] *albicans* and other *Candida* species. It exhibits no appreciable activity against bacteria.

Nystatin provides specific therapy for all localized forms of candidiasis. Symptomatic relief is rapid, often occurring within 24 to 72 hours after the initiation of treatment. Cure is effected both clinically and mycologically in most cases of localized candidiasis.

INDICATIONS AND USAGE
Nystatin Ointment is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* [Monilia] *albicans* and other *Candida* species.

CONTRAINDICATIONS
Nystatin Ointment is contraindicated in patients with a history of hypersensitivity to any of its
PRECAUTIONS
Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.
This preparation is not for ophthalmic use.

ADVERSE REACTIONS
Nystatin is virtually non-toxic and nonsensitizing and is well tolerated by all age groups including debilitated infants, even on prolonged administration. If irritation on topical application should occur, discontinue medication.

DOSAGE AND ADMINISTRATION
Nystatin Ointment should be applied liberally to affected areas twice a day or as indicated until healing is complete. Nystatin cream is usually preferred to nystatin ointment in candidiasis involving intertriginous areas; very moist lesions, however, are best treated with nystatin topical powder.
This preparation does not stain skin or mucous membranes and provides a simple, convenient means of treatment.

HOW SUPPLIED
Nystatin Ointment (100,000 USP Nystatin Units per gram) is a yellow ointment available as follows:
NDC 0168-0007-15 15 gram tube
NDC 0168-0007-30 30 gram tube
Store at controlled room temperature 15°-30°C (59°-86°F).

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747
I20715H
R08/11
#21

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CONTAINER
NDC 0168-0007-15
FOUGERA®
NYSTATIN OINTMENT USP
100,000 USP Nystatin Units Per Gram
For Topical Use Only.
Not for Ophthalmic Use.
Rx only
CONTAINS: 100,000 USP
Nystatin Units per gram,
in a polyethylene and
mineral oil base.

NET WT 15 grams
NYSTATIN
nystatin ointment

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: TOPICAL

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>nystatin (UNII: BDF1O1C72E)</td>
<td>nystatin</td>
<td>100,000 [USP] in 1 g</td>
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Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
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<tr>
<td>HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)</td>
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<td>Mineral Oil (UNII: T5L8T28FGP)</td>
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Packaging

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**Labeler** - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 11/2018  E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.